

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NORTHERN ILLINOIS**

ASTELLAS US HOLDING, INC., and)	
ASTELLAS PHARMA US, Inc.)	
)	
)	
Plaintiffs,)	
)	Case No. Case No. 1:17-cv-08220
vs.)	
)	Judge Honorable Manish S. Shah
STARR INDEMNITY AND LIABILITY)	
COMPANY,)	
)	
and)	
)	DEMAND FOR JURY TRIAL
BEAZLEY INSURANCE COMPANY, INC.,)	
)	
and)	
)	
FEDERAL INSURANCE COMPANY,)	
)	
Defendants.)	

AMENDED COMPLAINT

1. Plaintiffs, Astellas US Holding, Inc. (“ASUH”) and Astellas Pharma US, Inc. (“APUS”) (ASUH and APUS are referred to collectively herein as “Astellas” or the “Company”), for their Complaint against Defendants, Starr Indemnity and Liability Company (“Starr”), Beazley Insurance Company, Inc. (“Beazley”), and Federal Insurance Company (“Federal”), state as follows:

NATURE OF THE ACTION

2. In this action, Astellas seeks compensatory damages for Starr’s breach of its duties under an insurance policy it issued to Astellas, which provides broad coverage for defense

costs arising from alleged **Wrongful Acts**¹ by Astellas. Astellas seeks damages it suffered due to Starr's refusal to reimburse Astellas for **Defense Costs** (i.e., covered defense and investigation costs) that Astellas incurred, and continues to incur, to defend and investigate a **Claim** asserted by the United States Government for alleged Federal health care offenses. Astellas also seeks a declaration that Beazley, whose policy is excess to Starr's, must indemnify Astellas for all **Defense Costs** relating to this **Claim** in excess of the retention and the underlying limit of \$5 million, up to its policy's limit of \$5 million. Finally, Astellas seeks a declaration that Federal, whose policy is excess to Starr's and Beazley's, must indemnify Astellas for **Defense Costs** relating to this **Claim** upon exhaustion of the \$10 million in underlying limits, up to its policy's limit of \$10 million.

THE PARTIES

3. AUSH is a corporation organized and existing under the laws of Delaware, with its principal place of business in Northbrook, Illinois.

4. APUS is a corporation organized and existing under the laws of Delaware, with its principal place of business in Northbrook, Illinois.

5. Starr is a corporation organized and existing under the laws of Texas, with its principal place of business in New York, New York.

6. Beazley is a corporation organized and existing under the laws of Connecticut, with its principal place of business in Farmington, Connecticut.

7. Federal is a corporation organized and existing under the laws of Indiana, with its principal place of business in Warren, New Jersey. (Starr, Beazley and Federal are collectively referred to herein as "Defendants").

¹ Terms in bold letters shall have the meanings ascribed to them in Exhibit A.

JURISDICTION AND VENUE

8. This Court has jurisdiction over the claims asserted in this Complaint pursuant to 28 U.S.C. § 1332 because Astellas is not a citizen of the same states as Defendants, and the amount in controversy exceeds \$75,000, exclusive of interests and costs.

9. Venue is proper in the District of the Northern District of Illinois because a substantial part of the events and transactions giving rise to the controversy occurred in Illinois, as required by 28 U.S.C. § 1391. Among other things, Defendants delivered the insurance policies at issue to Astellas's offices in Illinois; Astellas approved and initiated payment of premiums for the policies from Illinois; and the financial harm to Astellas as a result of Starr's wrongful conduct occurred and is occurring in Illinois.

10. Personal jurisdiction in Illinois is proper because, at all relevant times, Defendants have been licensed or authorized to sell insurance in and have transacted business in Illinois, including with Astellas as to the policies at issue in this action. Defendants also performed acts within Illinois for the purpose of realizing pecuniary benefit, namely contracting to insure persons, property, or risks located in Illinois, including collecting premiums for the policies at issue in this action.

THE STARR POLICY

11. Starr provided Directors and Officers Liability Coverage ("D&O Coverage") under a "Resolute Portfolio For Private Companies" insurance policy to Astellas for the period April 1, 2015 to April 1, 2016 (the "Starr Policy," Exhibit A). Subject to its terms and conditions, the Starr Policy provides a \$5 million limit of liability excess of a \$500,000 self-insured retention.

12. The applicable insuring agreements in the Starr Policy provide, in relevant part:

1. INSURING AGREEMENTS

- A. The **Insurer** shall pay on behalf of any **Insured Person** the **Loss** arising from a **Claim** first made during the **Policy Period** . . . against such **Insured Person** for any **Wrongful Act**, and reported to the **Insurer** in accordance with the terms of this policy, except if the **Company** has indemnified the **Insured Person** for such **Loss**.
- B. The **Insurer** shall pay on behalf of the **Company** the **Loss** arising from a **Claim** first made during the **Policy Period** . . . against any **Insured Person** for any **Wrongful Act**, and reported to the **Insurer** in accordance with the terms of this policy, if the **Company** has indemnified the **Insured Person** for such **Loss**.
- C. The **Insurer** shall pay on behalf of the **Company** the **Loss** arising from a **Claim** first made during the **Policy Period** . . . against the **Company** for any **Wrongful Act**, and reported to the **Insurer** in accordance with the terms of this policy.

(Policy, D&O Liability Coverage Section, at p. 1.)

13. The term “**Claim**” is expansively defined to include any “(1) written demand for monetary, non-monetary or injunctive relief made against an **Insured**.”

14. The term “**Wrongful Act**” is also defined broadly as, in relevant part:

- (1) with respect to an **Insured Person**, any actual or alleged act, error, omission, neglect, breach of duty, breach of trust, misstatement, or misleading statement by an **Insured Person** in his or her capacity as such or any matter claimed against an **Insured Person** by reason of such capacity;

* * *

- (3) with respect to the **Company**, any actual or alleged breach of duty, neglect, error, misstatement, misleading statement, omission or act by the **Company**.

15. The term “**Loss**” includes “damages, settlements or judgments” and “**Defense Costs**.” **Defense Costs** means “reasonable and necessary fees, costs, charges or expenses resulting from the investigation, defense or appeal of a **Claim**.”

16. **General Condition 5, NOTICE OF CLAIM**, provides in relevant part:

The **Insured(s)** shall, as a condition precedent to the obligations of the **Insurer** under this policy, give written notice of a **Claim** . . . to the **Insurer** at the address set forth in Item 9 of the Declarations. * * *

With respect to the Directors & Officers Liability Coverage Section, the **Insured(s)** shall, as a condition precedent to the obligations of the **Insurer** under this policy, give written notice to the **Insurer** pursuant to this Clause 5, of a **Claim** made against an **Insured** as soon as practicable after the **Company's** general counsel or risk manager (or individuals with equivalent responsibilities) becomes aware of the **Claim**; however, in no event shall such notice be provided later than sixty (60) days after the expiration of the **Policy Period**. * * *

THE BEAZLEY AND FEDERAL POLICIES

17. Beazley provided excess D&O Coverage to Astellas under an “Excess Private Companies Insurance Policy” covering the period April 1, 2015 to April 1, 2016 (the “Beazley Policy,” Exhibit B). Except where it is specifically modified (not relevant here), the Beazley Policy follows the terms and conditions of the Starr Policy, providing a \$5 million limit of liability excess of the Starr Policy’s \$5 million limit of liability and the applicable \$500,000 self-insured retention. The Beazley Policy covers **Loss** (including **Defense Costs**) after all of the **Underlying Limits** (as that term is defined in the Beazley Policy) have been exhausted through payments of amounts covered under the Starr Policy.

18. Federal provided excess D&O Coverage to Astellas under an “Excess Policy” covering the period April 1, 2015 to April 1, 2016 (the “Federal Policy,” Exhibit C). Except where it is specifically modified (not relevant here), the Federal Policy follows the terms and conditions of the Starr Policy, providing a \$10 million limit of liability excess of the Starr Policy’s and the Beazley Policy’s combined limits of \$10 million and the applicable \$500,000 self-insured retention. The Federal Policy covers **Loss** (including **Defense Costs**) after all of the

Underlying Limits (as that term is defined in the Federal Policy) have been exhausted through payments of amounts covered under the Starr and Beazley Policies.

THE CLAIM

19. In November 2005, the Department of Health and Human Services, Office of Inspector General (“OIG”) issued a Special Advisory Bulletin titled “Patient Assistance Programs for Medicare Part D Enrollees” (the “OIG Bulletin”). The OIG Bulletin advised that beginning January 1, 2006, Medicare Part D would offer enrollees broad coverage for outpatient prescription drugs and Medicare beneficiaries who enroll in Part D would no longer be eligible to participate in patient assistance programs (“PAPs”) historically sponsored by pharmaceutical companies. The OIG Bulletin further stated:

Pharmaceutical manufacturers have expressed interest in continuing to assist Medicare Part D enrollees of limited means who do not qualify for the low-income subsidy.

OIG is mindful of the importance of ensuring that financially needy beneficiaries who enroll in Part D receive medically necessary drugs, and OIG supports efforts of charitable organizations and others to assist financially needy beneficiaries, as long as the assistance is provided in a manner that does not run afoul of the Federal anti-kickback statute or other laws. * * *

We have been asked whether the anti-kickback statute will be implicated if pharmaceutical manufacturer PAPs continue to offer assistance to financially needy Medicare beneficiaries who enroll in Part D by subsidizing their cost-sharing obligations for covered Part D drugs. For the reasons set forth below and consistent with extant OIG guidance, we conclude that pharmaceutical manufacturer PAPs that subsidize Part D cost-sharing amounts present heightened risks under the anti-kickback statute. However, in the circumstances described in this Bulletin, cost-sharing subsidies provided by *bona fide*, independent charities unaffiliated with pharmaceutical manufacturers should not raise anti-kickback concerns, even if the charities receive manufacturer contributions. In addition, we believe other arrangements described in this Bulletin, if properly structured, may pose reduced risk. Thus, we believe lawful avenues exist for pharmaceutical manufacturers and

others to help ensure that all Part D beneficiaries can afford medically necessary drugs.

20. In May 2014, OIG issued a Supplemental Special Advisory Bulletin on Independent Charity Patient Assistance Programs (the “Supplemental OIG Bulletin”). Among other things, the Supplemental OIG Bulletin stated:

We continue to believe that properly structured PAPs can help Federal health care program beneficiaries. This Supplemental Bulletin provides additional guidance regarding PAPs operated by independent charities (Independent Charity PAPs) that provide cost-sharing assistance for prescription drugs. To address some of the specific risks that have come to our attention in recent years, this guidance discusses problematic features of PAPs with respect to the anti-kickback statute, section 1128B(b) of the Act, and the provision of the Civil Monetary Penalties Law prohibiting inducements to Medicare and Medicaid beneficiaries (Beneficiary Inducements CMP), section 1128A(a)(5) of the Act. Other potential risk areas, including, for example, potential liability under the False Claims Act, 31 U.S.C. 3729–33, or other Federal or State laws, are not addressed here.

21. On March 3, 2016, the U.S. Department of Justice (the “Justice Department”) issued a subpoena to Astellas demanding certain documents relating to its ongoing industry-wide investigation of Astellas and other pharmaceutical companies for alleged “Federal health care offenses” (the “Subpoena”). A copy of the Subpoena is attached as Exhibit D.

22. The Subpoena is addressed to Astellas’s Japanese parent company, Astellas Pharma, Inc. (“API”). However, the Subpoena commands “You” to produce certain documents. The term “You” is defined to also include (among others) API’s subsidiaries. Because API never provided charitable contributions to the co-pay assistance foundations at issue in the Subpoena, the only relevant entity for purposes of the Subpoena was APUS, which is a U.S.-based subsidiary of API. This was explained to the Justice Department, and thereafter the Justice Department and APUS agreed that the Subpoena would apply to APUS (an **Insured** under the

Policy). This agreement is reflected in the tolling agreement entered into between the Justice Department and APUS (further discussed *infra*).²

23. The Subpoena asserts that the documents were “necessary in the performance of the responsibility of the United States Department of Justice to investigate Federal health care offenses, defined in 18 U.S.C. § 24(a) to mean violations of, or conspiracies to violate: 18 U.S.C. §§ 669, 1035, 1347, or 1518; and 18 U.S.C. §§ 287, 371, 664, 666, 1001, 1027, 1341, 1343 or 1954 if the violation or conspiracy relates to a health care benefit program (defined in 18 U.S.C. § 24(b)).” The asserted “Federal health care offenses” in this case allegedly arise from charitable donations to Independent Charitable PAPs (as that term is used in the Supplemental OIG Bulletin).

24. Among other things, the Subpoena demanded that Astellas produce “[d]ocuments sufficient to show by date and amount all payments from Astellas to any 501(c)(3) organization that provides financial assistance to patients taking drugs sold by Astellas, and, where applicable, the specific fund or program within any such organization that received the payment or to which Astellas earmarked the payment.”

25. Because the Subpoena was issued under the authority of 18 U.S.C. § 3486, it constitutes an “authorized investigative demand,” which, by statute, can only be issued where there is an ongoing criminal investigation of “Federal health care offenses.” The Justice Department has specifically stated that before an “authorized investigative demand” can be issued, the U.S. Attorney must consider (1) “[w]hether the background of the criminal investigation for which the records are being subpoenaed relates to any act or activity involving a

² Under Condition 14 of the General Terms & Conditions Section of the Starr Policy, AUSH “shall act on behalf of all Insureds with respect to all matters as respects this policy,” and is a necessary and proper plaintiff to pursue APUS’s coverage claims.

Federal health care offense (as defined in 18 U.S.C. § 24(a)) as required by 18 U.S.C. § 3486,” and (2) “[w]hether appropriate consideration has been given to the manner in which to enforce the investigative demand in the event of noncompliance.” (U.S. Attorney Manual, Health Care Fraud, § 9-44.203, at <https://www.justice.gov/usam/usam-9-44000-health-care-fraud>.)

26. Astellas does not dispute that it provided charitable donations to independent 501(c)(3) organizations that assist financially needy patients, or that some of the patients assisted by those organizations may have taken drugs sold by Astellas. The dispute is whether those donations constituted “Federal health care offenses.” Astellas maintains that its donations were lawful and appropriate and were made for the purpose of contributing to the pharmaceutical safety net for financially needy patients, and that the donations were made in a manner consistent with the guidance previously provided in the OIG Bulletin and, subsequently, the Supplemental OIG Bulletin.

27. While the Justice Department has acknowledged that donations by pharmaceutical manufacturers to Independent Charity PAPs are not *per se* illegal, the Justice Department has told Astellas that it contends that Astellas’s charitable donations to Independent Charity PAPs violated the law and did not comport with the Special Advisory Bulletins issued by the OIG.

28. The Justice Department’s view that such charitable donations to Independent Charity PAPs (like those it contends were made by Astellas and other pharmaceutical manufacturers) violate the law is also evidenced by the Justice Department’s statements regarding its investigations of pharmaceutical manufacturers, where the Justice Department has asserted that those companies violated the law by paying kickbacks to Medicare patients through Independent Charity PAPs. For example, in the December 19, 2017 settlement agreement between United Therapeutics’ and the United States, the United States contends: “UT made

donations to CVC's³ PAH fund and used it as a conduit to pay the copay obligations of thousands of Medicare patients taking the Subject Drugs, to eliminate price sensitivity of patients purchasing or physicians prescribing the Subject Drugs, and to induce those patients' purchases of the Subject Drugs." According to Principal Deputy Assistant Attorney General Chad A. Readler's statement in the press release announcing UT's settlement, "the government will hold accountable drug companies that attempt to use illegal kickbacks to defeat mechanisms Congress designed to act as a check on drug pricing and healthcare costs."

29. Astellas's contributions to Independent Charity PAPs—the precise subject of the Subpoena—are alleged by the Justice Department to violate applicable law, and accordingly constitute **Wrongful Acts**.

30. The Justice Department continues to pursue its investigation of Astellas's practices regarding its charitable donations to 501(c)(3) organizations, and it has subpoenaed additional documents.

31. On October 19, 2017, the Justice Department requested that Astellas enter into a Limited Tolling Agreement on Statute of Limitations (the "DOJ Limited Tolling Request"). Astellas and the Justice Department entered into a tolling agreement on October 26, 2017. The executed tolling agreement states that, "[a]s you are aware," the Justice Department "is currently conducting a joint criminal and civil investigation of [] Astellas, and its officers, employees, and agents." It also states that "[t]he conduct being investigated includes, without limitation, the possible violation by Astellas and certain of its officers, employees, and agents of various federal criminal statutes, including, but not limited to, 42 U.S.C. § 1320a-7b (anti-kickback statute) and 18 U.S.C. § 1347 (health care fraud), and certain civil statutes, including, but not limited to, 31

³ During the relevant time period, Caring Voices Coalition ("CVC") was an Independent Charity PAP that provided co-pay assistance to financially needy patients.

U.S.C. § 3729-33 (False Claims Act), in connection with Astellas's payments to '501(c)(3)' organizations that provide financial assistance to Medicare beneficiaries."

32. The DOJ Limited Tolling Request also constitutes a **Claim** under the Starr Policy and, because it arises from the same **Wrongful Acts** set forth in the Subpoena, it relates back to the Starr Policy, as well as the Beazley and Federal Policies. Astellas promptly provided notice of the DOJ Limited Tolling Request to Defendants.

33. The legal fees and expenses that Astellas has incurred since March 3, 2016 arose from Astellas's defense of the alleged **Wrongful Acts** set forth in the Subpoena and its investigation of the facts and circumstances implicated by the Subpoena. In addition, Astellas has advanced costs for individual counsel for certain of its employees and officers for their defense of these allegations. In total, the Defense Costs incurred by Astellas exceed \$10.5 million, the underlying limits of the Federal Policy.

DEFENDANTS' DENIALS OF COVERAGE

34. On or about March 11, 2016, and as soon as practicable, Astellas (through its broker Marsh USA Inc.) gave each of the Defendants timely written notice of the Subpoena.

35. On March 28, 2016, Beazley reserved its rights, noting that, "[a]s an excess carrier, Beazley cannot have any coverage obligations until the underlying layer is exhausted. Accordingly, we ask that you provide us with a copy of the primary carrier Starr's coverage position issued with respect to this matter. Upon receipt and review of the same, we will provide you with a more detailed coverage analysis on behalf of Beazley."

36. On March 15, 2016, Federal acknowledged receipt of the notice and stated that "it must reserve the right to raise all of the defenses available to it under the policy and the law."

37. On March 29, 2016, Starr denied coverage, asserting that "the Subpoena does not currently fall within the scope of coverage afforded by the Policy." Specifically, Starr asserted

that “the definition of **Claim** requires that, at the very least, there must be a written demand for monetary, non-monetary or injunctive *relief* (emphasis added) made against an **Insured**. Here, there has been no written demand for relief made against any **Insured** . . . The Subpoena simply requests that certain documents be produced.”

38. Beazley and Federal have both subsequently adopted the coverage positions and all reservations of rights and defenses asserted by Starr in its March 29, 2016 letter.

39. Starr’s assertion that the Subpoena “simply requests that certain documents be produced” is wrong. The Subpoena constitutes a “command” to produce documents by the government—it is not a mere request. As noted above, the statute authorizing the issuance of such subpoenas, 18 U.S.C. § 3486, deems such subpoenas “investigative demands.” Indeed, the Subpoena warns that “[f]ailure to comply with the requirements of this subpoena will render you liable to proceedings in the district Court of the United States to enforce obedience to the requirements of this subpoena, and to punish default or disobedience.” A subpoena under 18 U.S.C. § 3486 is therefore not a mere request for information, but a substantial demand for compliance by a federal agency with the ability to enforce its demand.

40. Further, the Subpoena constitutes a demand for *relief*, as required for coverage under the Policy. The phrase “a written demand for . . . non-monetary relief” is a broad one that includes a written demand for something that the respondent (allegedly) has a legal obligation to provide. The Justice Department thus claims a right to the subpoenaed documents, and the Subpoena specifically threatens liability in federal district court for failure to provide those subpoenaed documents.

**FIRST CAUSE OF ACTION:
BREACH OF CONTRACT AGAINST STARR**

41. Astellas repeats and re-alleges the allegations of paragraphs 1 through 35 hereof as if they were fully set forth herein.

42. The Subpoena constitutes a written demand for non-monetary relief. Namely, it demands that Astellas undertake certain actions to produce documents, all in the manner required by the instructions set forth in the Subpoena. Accordingly, the Subpoena constitutes a **Claim** as that term is defined in the Starr Policy.

43. Astellas's acts set forth above, including the challenged donations to Independent Charity PAPs, constitute **Wrongful Acts** as that term is defined in the Starr Policy because they constitute "actual or alleged . . . act[s] by the **Company**."

44. The reasonable and necessary costs of defending against and investigating the alleged "Federal health care offenses" being investigated by the Justice Department constitute **Defense Costs**, and therefore constitute covered **Loss** under the Starr Policy.

45. The **Defense Costs** that Astellas has incurred to date exceed the applicable retention in the Starr Policy.

46. Astellas has complied with all applicable conditions of the Starr Policy.

47. Starr has refused to pay the amounts owed under the Starr Policy.

48. By reason of the foregoing, Starr is in breach of its contractual obligations under the Starr Policy, and Astellas has incurred damages as a direct result of that breach.

**SECOND CAUSE OF ACTION
DECLARATORY JUDGMENT AGAINST BEAZLEY AND FEDERAL**

49. Astellas repeats and re-alleges the allegations of paragraphs 1 through 43 hereof as if they were fully set forth herein.

50. Astellas's defense and investigation of this **Claim** is ongoing. The total **Defense Costs**, after deducting the self-insured retention, have exceeded the respective **Underlying Limits** of the Federal Policy and the **Limits of Liability** of the Beazley Policy.

51. With respect to the Subpoena, the Beazley and Federal Policies, as follow-form policies, provide the same scope of coverage as the Starr Policy.

52. Section 1 of the Declaratory Judgment Act, 28 U.S.C. §§ 2201 et seq., provides in relevant part:

In a case of actual controversy within its jurisdiction, . . . any court of the United States . . . may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such.

53. Because Beazley and Federal have refused to acknowledge coverage for **Defense Costs** incurred in connection with the Subpoena, an actual controversy exists by and among Astellas, Beazley and Federal regarding Beazley's and Federal's respective obligations to pay **Defense Costs** incurred in connection with the Subpoena.

54. Astellas therefore seeks a declaration that Beazley and Federal must pay, on Astellas's behalf, all reasonable and necessary costs of investigating and defending this **Claim**, up to each Defendant's respective limit of liability.

JURY TRIAL DEMAND

55. Astellas, pursuant to Rule 38 of the Federal Rules of Civil Procedure, demands trial by jury on all issues triable of right by a jury.

PRAYER FOR RELIEF

WHEREFORE, Astellas respectfully prays for the following:

A. Judgment in favor of Astellas and against Starr on this Complaint, in an amount to exceed \$75,000;

B. A declaration that Beazley and Federal must pay up to their respective limits, on behalf of Astellas, covered **Defense Costs** that Astellas has incurred and will incur in the future in defending and investigating the Subpoena; and

C. An Order awarding Astellas such other and further relief as the Court deems just and proper, including, but not limited to, prejudgment interest at the applicable rate for amounts due and owing, and the costs and expenses associated with bringing this claim.

Astellas US Holding, Inc. and
Astellas Pharma US, Inc.

/s/ James A. White
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